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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/623,176	07/18/2003	Elsa A.J.M. Goulmy	2183-6047US	4726

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EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT PAPER NUMBER

1644

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/623,176

Applicant(s)

GOULMY ET AL.

Examiner

Michael Szperka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7 and 49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7 and 49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment and response received January 9, 2006 is acknowledged.
Claims 1-6, 8-48, and 50 have been canceled.
Claims 7 and 49 have been amended and are pending in the instant application.

Specification

2. Applicant is thanked for the amendments to the specification received January 9, 2006 to address and correct issues raised in the office action mailed July 8, 2006.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

The claim objections of record have been obviated by applicant's cancellation or amendment of the claims as per the claim amendments received January 9, 2006.

Claim Rejections - 35 USC § 112

3. The rejections of claims 7 and 49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the inclusion of new matter and for

lack of possession of the claimed invention have been withdrawn in view of applicant's claim amendments received January 9, 2006.

4. Claims 7 and 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of mitigating graft rejection and Graft versus Host Disease (GvHD) by administering the 9 amino acid peptide consisting of SEQ ID NO:2, does not reasonably provide enablement for methods of preventing graft rejection or GvHD by administering longer peptides that comprise SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed January 9, 2006 have been fully considered but they are not persuasive. Specifically, applicant's amendment of the claims received January 9, 2006 has obviated many, but not all, of the issues discussed in the rejection of record set forth in the office action mailed July 8, 2005.

Applicant has amended the claims to better indicate the intended patient population, the conditions that are to be treated, and the identity and mode of delivery of the peptide used in applicant's method of tolerance induction. However, the claim still recites that performing applicant's method prevents graft rejection and GvHD. In the enablement rejection of record, evidence was presented to applicant indicating that many minor Histocompatibility antigens (mHag) are known in the art to exist, and that even if the graft material is HLA matched to the recipient and the HA-1 allele present in

the graft is known, graft rejection and GvHD will still occur due to vigorous immune responses directed to other mHags. Applicant's response does not appear to address this issue or provide evidence to counter the teachings made of record in office action mailed July 8, 2006. Note that the specification appears to define a HA-1 negative individual as one who does not have the HA-1^H allele (i.e. the patient has the HA-1^R allele which comprises the sequence VLRDDLLEA, SEQ ID NO:10, which does not appear to be recognized by CTL when presented to the immune system in any HLA molecule, see particularly Example 1 beginning on page 36 of the specification). Clear data is provided in the specification that the 9 amino acid peptide consisting of SEQ ID NO:2 binds to and can be presented to the immune system by HLA-A2.1. It is known in the art that nine amino acids is the preferred length for binding to MHC class I molecules, with binding affinity decreasing rapidly with longer or shorter peptides (Goldsby et al., immunology, 5th edition, 2003, pages 170-171, see entire selection, particularly the paragraph that spans the left and right columns of page 171). Applicant has not demonstrated that longer peptides comprising SEQ ID NO:2 are still capable of binding to HLA-A2.1, and if the administered peptides cannot be bound and presented to the immune system by the appropriate restriction element, namely HLA-2.1, it is not clear what therapeutic benefit will be achieved in the patient.

Therefore, given the lack of working examples concerning the administration of the peptide consisting of SEQ ID NO:2 in graft settings, the lack of data concerning the binding of longer peptides comprising SEQ ID NO:2 to be bound and presented by HLA-2.1, and the fact that other mHags contribute to graft rejection and GvHD in addition to

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HA-1, a skilled artisan would be unable to practice the full scope of applicant's claimed method without conducting an undue amount additional research.

5. No claims are allowable.

6. Applicant's amendment necessitated the new ground of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Szperka, Ph.D.
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Technology Center 1600
April 10, 2006


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